REMARKS

As an initial matter, applicants request that the Examiner indicate on the record that the claim amendments submitted on October 4, 2002, have been entered. In an Office Communication dated November 7, 2002, the Examiner indicated that the amendments will be entered upon filing of the Notice of Appeal. The Notice of Appeal, however, was filed on November 4, 2002, but there is no indication of record that the claim amendments dated October 4, 2002 have been entered.

There is no indication on the record that these amendments have been considered. Applicants file this Request for Continued Examination (RCE) to request that the claim amendments dated October 4, 2002, be considered. Furthermore, applicants submit the above amendments to remove the superfluous language in Claim 1, and to further clarify that the claimed fertilized oocytes and embryonic stem cells are both of mouse origin.

Applicants continue to respectfully submit that the claims are in condition for allowance. The Examiner, however, in a telephone conversation on April 3, 2003, with the undersigned, indicated that the rejections remain for lack of enablement under 35 U.S.C. § 112, ¶ 1. The Examiner indicated that the reason for maintaining such a rejection is that Claim 1 does not recite a phenotype of the transgenic mouse produced pursuant to the claimed method, referring to page 15 of the Office Action dated June 4, 2002.

Applicants respectfully submit that it is improper to maintain the lack of enablement rejection.

The test for enablement under 35 U.S.C. § 112, ¶ 1 is whether there is a need for undue or unreasonable experimentation for an ordinarily skilled person in the relevant art to make and use, or otherwise practice the claimed invention. *See* e.g. *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988).

Claim 1, the broadest claim, recites a method for producing a transgenic mouse overexpressing a polypeptide having platelet-derived growth factor C (PDGF-C) activity by introducing a DNA into a mouse pronuclei cell of a fertilized oocyte, and allowing the cell to develop into a transgenic mouse, wherein the fertilized oocyte is further implanted into a pseudopregnant mouse. Alternatively, an embryonic stem cell is used, and DNA is allowed to integrate into a genomic DNA of the embryonic stem cell; and the embryonic stem cell is introduced into a developing embryo.

Given the instant disclosure and the state of the art as of the filing date of the instant application, an ordinarily skilled person in the art can easily follow the teachings in the specification and perform the method as claimed without any undue experimentation, and produce a transgenic mouse overexpressing the PDGF-C DNA. This overexpression of the DNA is itself a phenotype of the mouse so produced.

During the telephone conversation, the Examiner seemed to indicate that a "phenotype" of hypertrophy or cardiac fibrosis should also be recited in the claim to satisfy the enable requirement.

Applicants respectfully disagree. Whether the transgenic mouse produced according to the claimed method exhibits hypertrophy or cardiac fibrosis is not relevant to the enablement analysis under 35 U.S.C. § 112, ¶ 1. The claimed method is enabled unless the Examiner can show that the PDGF-C-overexpressing mouse so produced lacks *any* utility under 35 U.S.C. § 101. In fact, as taught in the Specification (see e.g. page 10, first paragraph), a mouse overexpressing PDGF-C can be used for other purposes, such as the study of the function of PDGF-C and the effect of its overexpression on animals, in addition to the effect on the heart.

Indeed, cardiac fibrosis is only one of many possible changes overexpression of PDGF-C may cause in an animal, and as with other aspects of heart anatomy, its development depends highly on the age of the animal. In

other words, the development of cardiac fibrosis is neither necessary in a transgenic mouse produced by the instantly claimed methods, nor is it commensurate with scope of the instant invention. Thus, adding a recitation of this or other type of "phenotype" to the claimed method not only unduly limit the claimed method, it also adds ambiguity to the scope of the claims.

Accordingly, applicants respectfully submit that rejection of the claims as amended for not reciting a "phenotype" as a basis of lack of enablement under 35 U.S.C. § 112, ¶ 1 is improper. Because no other rejections are outstanding, applicants respectfully submit that all claims are in condition for allowance and earnestly solicit an early indication from the examiner to that effect.

If there are any questions regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323 (Docket #1064/48487).

Respectfully submitted,

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